IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Applicant:	William S. Dworzan
Examiner/ AU:	Gary K. Graham/ 1744
Application Title:	TOOTHBRUSH WITH TUNED VIBRATING HEAD
Agent Docket No.:	Dworza.W-01

PETITION TO MAKE SPECIAL MPEP 708.02 (VIII)

Mail Stop: Petitions
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PO Box 1450
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Commissioner for Patents:

Pursuant to 37 C.F.R. Section 1.102(d) and M.P.E.P. 708.02 VIII (Accelerated Examination), Applicant hereby files this petition in the United States Patent and Trademark Office to make special the prosecution in the above-identified case. This petition is based on the grounds that the claims in this application are believed to be drawn to a single invention, namely, an apparatus (claims 1-11). However, if the Office determines that all claims presented are not obviously directed to a single invention, applicant will make an election, without traverse.

Applicant has conducted a pre-examination patentability search in the following fields of search by class/subclass: 15/21.1, 22.1, 22.2, 22.3, 22.4, 22A, 22C, 22R, 23, 24, 28, 29, 167.1; 128/36; 132/321, 322; 200/157, 502, 542, 543, 544, 537, 560, 573; 310/10, 20, 27, 36, 37, 39, 81; 433/122, 123, 216; 464/29; 601/ 67, 68, 69, 70, 87, 139, 141, 142 and international classes A61C 15/00, 17/00; 17/34; A46B 13/02; A61H 13/00; B08B 13/02. Applicant has also conducted a general literature search. The relevant references found in our searches are submitted herewith and are discussed below and it is pointed out with particularity, how the claimed subject matter distinguishes over these references. Based on our search results, it is applicant's opinion that all of the claims in this application are allowable.

Hahn, U.S. 5651157 teaches the use of a moving weight that is manually moved to adjust the magnitude of vibration at the brush wherein the motion is generated at the base of a brush neck. However, Hahn does not consider or teach the matching of motor speed to the natural frequency of vibration of the brush head.

Hubner, U.S. 3685080 teaches primarily the case and electrical connection details of an electric toothbrush with rotational motion set up at the base of a brush neck.

Okada, U.S. 5,421,726 teaches a comfort index and a cleaning effectiveness index both with respect to vibration frequency of an electric toothbrush and shows a method in which one may optimize a result where vibration is generated at the base of a brush neck.

Okada, U.S. 5706542 teaches primarily the mechanical parts of the toothbrush and means for vibrating a brush neck from its base via a rotational mass.

Sugimoto et al, 5718667 teaches a dental hygiene brush that is caused to vibrate by a rotating mass set at the base of a brush wire.

Each of the above five references teach methods of generating vibration in an electric toothbrush by spinning a mass at or near the base of a brush neck. This is distinctly different from the subject invention, which generates vibration directly at the brush itself by an offset weight that causes the brush to move with eccentric motion and has the great advantage of using less energy for producing effective brushing.

Giuliani et al., U.S. 5,189,751 describes a vibrating toothbrush, which uses an oscillator to drive a permanent magnet assembly in vibratory motion. No attempt to made to couple to the natural frequency of the brush neck.

Hahn, et al., U.S. 5,987,681 describes an electric toothbrush with a handle, a brush head and a shank, which connects the handle to the brush head. A rotary motor is arranged in the handle and drives an unbalanced mass. The unbalanced mass driven by the motor is

supported on one side or on both sides in the shank close to the brush head and is driven via an extended drive shaft, preferably an intermediate shaft, by the motor. However, again, no attempt is made to couple to the natural frequency of the brush neck.

McDougall, U.S. 6,421,866 describes an electric toothbrush having a balanced mass provided on a shaft extension that rotates freely about a longitudinal axis, inside a cavity in a brush head. The shaft extension and the brush head are flexibly coupled to a drive shaft and to a remote end of a shank respectively. When the shaft is rotated by an electric motor in a handle, of the toothbrush, an offset stub axle, effectively at a remote end of the shaft extension and fitted to a bearing in the brush head, causes the brush head to vibrate. The shank is not caused to vibrate to any extent. In this patent, no attempt is made to couple the natural frequency of vibration of the bush head or neck.

The above three references teach motorized toothbrushes providing vibratory motion to a toothbrush head as conducted through rotation of a mass in the brush head itself and this is similar to the subject invention. However, these references do not teach matching the rotational speed of the motor to the natural resonance frequency of the toothbrush head. Also, the references do not teach replaceable bristles that slide into an axial receiver.

Wolf, Susan, Hendrix, Ph.D., Suzanne (1998). Automated Toothbrush Comparison Statistical Report. Clinical Research Associates, describes an evaluation of 6 toothbrushes that was performed using two populations to determine if toothbrushes with sonic or ultrasonic capabilities reduce dental plaque more effectively than a manual or other automated toothbrushes. The Sensonic (Teledyne) and Sonicare (Optiva) toothbrushes claim sonic capabilities and the Ultrasonex (Sonex) claims ultrasonic capabilities. Control toothbrushes were the Interplak (Corsair) and Ultra Plaque Remover (Braun), which are automated toothbrushes not claiming sonic or ultrasonic capabilities, and the Advantage (Oral-B) manual toothbrush. Population one consisted of 24 non-handicapped subjects, while Population two consisted of 24 institutionalized handicapped subjects. Non-handicapped subjects were included to represent the majority of the population, while handicapped subjects were included because they have been reported as having frequent

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problems with heavy plaque in their oral cavities due to lack of manual dexterity necessary for effective tooth brushing.

Staff. (1998, July). CRA Status Report: Toothbrushes, Sonic & Ultrasonic. CRA Newsletter. P. 2-3, provides a comparison between sonic, ultrasonic, and manual toothbrushes. CRA laboratory & clinical studies compared plaque removal capability, test subject preferences, durability, & maintenance of 6 different toothbrushes over a 1 1/4 year period.
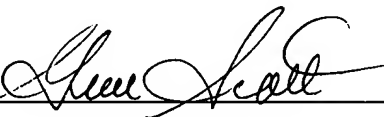
The above two references are of interest but do not provide any information concerning the use of matching of head resonance to rotational speed in an electric toothbrush.

In summary, in accordance with the above remarks, we find that the instant invention clearly distinguishes over the foregoing references found in our preliminary patentability search with respect to 35 USC 102. Additionally, we find that no combination of elements borrowed from these references, under 35 USC 103 could be construed to teach the instant invention.

Check No. 2323 including an amount of $130.00 to cover the required fee for a 37 C.F.R. Section 1.102(d) petition, for a small entity, is enclosed herewith. Please advise if any additional fees are required, or overpayment refund due.

In view of the above, applicant hereby petitions that the above-cited application be made special and advanced for examination, and applicant advised thereof.
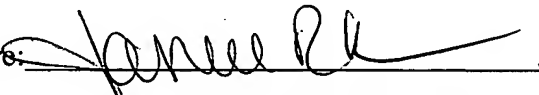
Very respectfully,

Gene Scott, 37,930 Agent of record

Please direct all communications to Customer Number 22197: Mr. Gene Scott, Patent Law & Venture Group, 3140 Red Hill Avenue, Suite 150, Costa Mesa, CA 92626-3440. Phone: (714) 668-1900; Fax: (714) 668-0583

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CERTIFICATION

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express mail in an envelope addressed to: "Mail Stop: Petitions, Commissioner For Patents, PO Box 1450, Alexandria, VA 22313-1450," on May 26, 2004, date of deposit.

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
CRA STATUS REPORT

TOOTHBRUSHES, SONIC & ULTRASONIC

Sonic & ultrasonic claims initiated a new generation of electric toothbrushes. Promotions promise superior plaque removal, minimal maintenance, & high levels of user acceptance. Validation of superiority is needed since costs are about 50 times that of conventional manual toothbrushes. CRA laboratory & clinical studies compared plaque removal capability, test subject preferences, durability, & maintenance of 6 different toothbrushes over a 1½ year period. Following report includes: (1) Listing of test methods; (2) Comparison of toothbrushes evaluated; (3) Important overall observations; & (4) CRA Conclusions.

1. LISTING OF TEST METHODS (See CRA website for methods & results at www.cranews.com)

There is no international standard test of toothbrush efficacy. Without designated test methods, valid controls, & quantitative methods that produce permanent records of clinical conditions, tests cannot be replicated & relative efficacy cannot be determined. This has lead to unwarranted & unsubstantiated claims that confuse & deceive both dental clinicians & the general public. Tests performed by CRA are outlined below:

A. <u>Clinical tests evaluating plaque removal.</u> 24 non-handicapped adults 21-59 years & 24 handicapped adults 22-57 years received professional prophylaxis followed by use of all 6 toothbrushes in random order in six 6-week test periods, each separated by 2-weeks using brushes they owned & used prior to the study. Initially & at 5 & 6 weeks, plaque was stained, photographed using an intraoral camera, quantified using image analysis software, & data were analyzed statistically.

B. <u>User surveys evaluating toothbrush design, durability, maintenance, & usefulness of unique features.</u> Non-handicapped participants listed their observations, preferences, & problems with each toothbrush on questionnaires after each test period & again at completion of entire study.

C. <u>Laboratory tests to determine brushing time, force, interproximal cleansing ability, noise, durability, sonic & ultrasonic effects on microorganisms, frequency & brush motion, scanning electron microscope photos of bristles, & measurement of physical features.</u> Each test used different procedures which are listed on CRA's website.

2. COMPARISON OF TOOTHBRUSHES EVALUATED

Rating key: E = Excellent = 4, VG = Very Good = 3.5, G = Good = 3, F = Fair = 2, P = Poor = 1, Y = Yes, N = No

Overall Grade (Columns A-G averaged)	Brand Name / Brush Type & Company Name (Listed by Overall Grade)	Costs (Suggested Retail List Price for single user model)	Head Shape & Size	Bristles †	Timer	Warranty (months)	A. Plaque Removal	B. Comfort of Vibration	C. Ergonomics	D. Noise	E. Durability	F. Maintenance	G. Users Who Would Purchase Brush	User Observations — Advantages	User Observations — Disadvantages
3.8	ADVANTAGE CONTROL GRIP, #35 SOFT (CONTROL) — Manual — Oral-B Laboratories, Phone: 650-598-5000, Fax: 650-591-3396	$3	Length = 28mm, Width = 12mm, Height = 16mm	33 tufts, 54 per tuft, 0.19mm diam. Rounding on tips = E. Length: 6-12mm	N	0	G-VG	E	VG	E	E	E	92%	• 71% liked convenience, control, & ease of use. • 54% liked brush head. • 42% liked small handle & grip. • 33% reported no disadvantages. • Blue bristles indicate replacement needed. • 33% liked low cost. • Can drop without breaking. • Easy to travel with. • No fear of breakdown or dead battery.	• 21% reported bristles too soft. • 13% reported head too big. • 13% reported grip "not right".
3.0	BRAUN ORAL-B ULTRA, PERSONAL #D9511 (CONTROL) — Electric (no sonic or ultrasonic claims) — Braun Oral-B, Phone: 650-598-5000, Fax: 650-591-3396	$40 (includes 1 head) / $9.99 One head replacement	Length = 13mm, Width = 13mm, Height = 20mm	26 tufts, 52 per tuft, 0.14mm diam. Rounding on tips = E. Length: 7-8mm	Y 2 min	12	VG	G	E	F-G	VG	F-G	57%	• 74% liked small round brush head. • 61% liked vibration. • 39% liked handle & grip. • 30% liked that base stores 4 heads. • Blue bristles indicate when to replace head. • Lowest cost electric brush in study. • Provides hardware for wall mounting.	• 43% disliked rough sound. • 39% disliked two-button on/off control. • 17% reported bristles wore out in 6 week test. • 13% reported did not hold charge well.
2.6	ULTRASONEX PLUS — Electric (ultrasonic claims, used like manual) — Sonex International Corp., Phone: 914-279-7048, Fax: 914-279-8474	$99 (includes 1 head) / $4.33 One head replacement	Length = 26mm, Width = 12mm, Height = 19mm	35 tufts, 68 per tuft, 0.16mm diam. Rounding on tips = F. Length: 9mm	Y 3 min	12	G-VG	VG	F	F	G	G	0%	• 27% liked control gained by manual operation. • 27% liked small charging base.	• 64% disliked large brush head. • 64% disliked recharging after each use. • 57% disliked no on/off button. (Newer models include a start control.) • 50% disliked buzzing sound. • 41% disliked handle & grip. • 32% disliked that brush appeared to do nothing.
2.3	INTERPLAK PERSONAL (CONTROL) — Electric (no sonic or ultrasonic claims) — Conair Corp., Phone: 732-389-4500, Fax: 732-389-4998	$45 (includes 1 head) / $12 One head replacement	Full Size Head Model: Length = 25mm, Width = 16mm, Height = 20mm	10 tufts, 213 per tuft, 0.13mm diam. Rounding on tips = E. Length: 6-11mm	Y 2 min	24	G-VG	G	G	P	G	G	42%	• 38% liked easy on/off control. • 29% liked base storage of 2 heads. • 29% liked 2 minute timer. • 17% liked plastic head cover. • Only brush with replaceable battery. (Manufacturer prefers to perform replacement.) • Can be wall mounted	• 75% disliked rough sound. • 50% disliked large brush head (a smaller Compact Head is available). • 46% disliked vibration. • 42% disliked large handle & grip. • 33% reported oily/metallic taste. • 29% reported brush head stalls easily. • 29% reported did not hold charge well. • 13% reported bristle tufts too far apart.
2.3	SENSONIC #SR-200W — Electric (sonic claims) — Teledyne Water Pik, Phone: 970-484-1352, Fax: 970-221-8715	$150 (includes 4 heads) / $9.50 One head replacement	Length = 25mm, Width = 13mm, Height = 19mm	26 tufts, 48 per tuft, 0.18mm diam. Rounding on tips = G. Length: 7-11mm	Y 2 min	24	VG	P	F-G	F-G	F-G	G	35%	• 39% liked easy on/off control. • 35% liked small brush head. • 35% liked 2-minute timer. • 26% reported held charge well. • 17% liked flat electric plug. • Only brush in study with indicator for battery charge level. • Base stores 4 heads • Provides hardware for wall mounting.	• 57% disliked vibration of bristles & handle. • 57% disliked buzzing sound. • 43% disliked large handle. • 13% reported brush stopped working during 6 week test. • Highest cost brush in study
2.2	SONICARE QP — Electric (sonic claims) — Optiva Corp., Phone: 435-401-2309, Fax: 435-401-4825	$100 (includes 2 heads) / $14.95 One head replacement	Plus Head: Length = 33mm, Width = 12mm, Height = 18mm	24 tufts, 70 per tuft, 0.14mm diam. Rounding on tips = G. Length: 6-11mm	Y 2 min	24	G	P	F	F	F	F-G	23%	• 45% liked 2 minute timer with beeps every 30 seconds to promote equal brushing time in all quadrants. • 45% liked small, heavy base. • 36% liked easy on/off control. • 18% liked plastic head cover.	• 73% reported vibration caused discomfort. • 64% disliked large brush head (smaller Junior Head is available). • 59% disliked large handle & no grip. • 59% disliked buzzing sound. • 27% reported splatter mess during use. • 23% reported brush is heavy. • Only automated brush tested with no light indicating that battery is charging.

† Bristle end finish analyzed using scanning electron microscope.   * See website for statistical groupings & significant interactions.

SUMMARY OF CHART:
Of six brushes tested, manual brush (Advantage Control Grip) received highest overall grade of Very Good to Excellent. Five electric brushes received overall grades ranging from Fair to Good (2.2 to 3.0). Users indicated a strong preference for purchasing manual brush (92%), citing ease of use, convenience, & low cost as reasons. Although the Ultrasonex operates like a manual brush, no user indicated desire to purchase it. Only manual brush had substantial number of users reporting no disadvantages (33%). Of electric brushes tested, users preferred small head & vibration of Braun Oral-B Ultra. They indicated a strong dislike for large brush heads, excessive vibration, & rough or buzzing noise.

3. IMPORTANT OVERALL OBSERVATIONS

A. <u>DESIGNATION OF A TOOTHBRUSH AS "SONIC" OR "ULTRASONIC" CAN BE MISLEADING.</u> Sonic refers to vibrations with a frequency between 20Hz & 20kHz. Four of the five electric brushes tested fall within this range, (Braun Oral-B Ultra, Interplak, SenSonic, Sonicare) & could be classified as "sonic", although two do not make sonic claims. Ultrasonic refers to vibrations with a frequency greater than 20kHz. The ultrasonic tooth brush in this study (Ultrasonex) operates at 1600kHz, but must be used as a manual brush. Relevance of sonic & ultrasonic energy to toothbrushing is unknown. Results of this study showed brushes with sonic & ultrasonic claims did not outperform the conventional manual toothbrush in plaque removal.

B. <u>NO BRUSH DESIGN PLEASED *ALL* USERS.</u> For example, some subjects preferred a larger head while others favored smaller heads, some preferred flat bristle plane & others liked uneven plane, some liked automated movement & others were annoyed by it.

C. <u>TOOTHBRUSH COST IS NOT A MEASURE OF PLAQUE REMOVAL.</u> Many believe cost of automated toothbrushes means they will clean teeth better. CRA study showed the manual toothbrush removed plaque as well as automated brushes.

D. <u>CONVENTIONAL MANUAL BRUSH IS "BEST BUY".</u> It does comparable job at least cost, & has convenience features desired by users.

E. <u>CLAIMS OF PLAQUE REMOVAL 4-6mm BEYOND BRISTLE TIPS COULD NOT BE CONFIRMED IN CRA'S TESTS.</u> *In-vitro* testing at 2, 4, & 6mm away from bristle tips at various pressures of 60, 100, 150, 200, & 320 grams force showed no significant differences.

F. <u>NEGATIVE SIDE EFFECTS FROM SONIC & ULTRASONIC ENERGY WERE *NOT* OBSERVED.</u> Problems such as loosening of crowns & orthodontic brackets & other adverse effects did not occur.

G. <u>ALL ELECTRIC TOOTH BRUSHES ARE SUSCEPTIBLE TO BREAKDOWN.</u> CRA study participants experienced 4% breakdown, including breakage from dropping, packing in suitcases, & excessive brushing pressure. or mechanical failure due to unknown causes.

H. <u>AUTOMATED TOOTHBRUSHES TESTED HAVE LESS MOVEMENT OF ENTIRE HEAD COMPARED TC TOOTHBRUSHES OF THE PAST.</u> This allows better intraoral access & ease of use, especially for manually impaired

I. <u>TIMERS ON TOOTHBRUSHES GENERALLY INSPIRE LONGER BRUSH TIMES.</u> Increased brush times can substantially improve plaque removal. CRA study used a 2 minute timer with <u>all</u> brushes tested throughout the study for all subjects. (CRA determined mean brush times by testing groups of subjects during brushing. Manual brush mean was 1 minute 20 seconds & automated brush mean was 1 minute 35 seconds.)

J. <u>SOME TEND TO USE AUTOMATED TOOTHBRUSHES LIKE A CONVENTIONAL MANUAL BRUSH</u> Automated brushes specify use of light pressure & slow movements for optimal performance. CRA study showec some subjects have trouble unlearning manual brush techniques. Heavier pressures used by some can slow or stall automated brushes & scrubbing motions can interfere with bristle actions.

K. <u>PLAQUE DISCLOSING DYE & INTRAORAL CAMERA HELPS PEOPLE IDENTIFY MISSED AREAS</u> Study subjects showed high interest in seeing areas where they missed plaque.

L. <u>CHARGING BASES & BRUSHES ARE NOT DESIGNED FOR FAST, EASY CLEANING.</u> Users noted it would be helpful if all parts of electric toothbrushes were dishwasher safe.

M. <u>MAINTENANCE NEEDS & EXPECTED USE-LIFE ARE NOT STATED CLEARLY.</u> Many users think automated brushes last indefinitely & only heads need changing. Actually, Ni-Cd batteries should be periodically discharged & recharged. Eventually batteries fail, causing brush to be discarded because batteries are sealed in. Of the brushes tested, only Interplak allows worn out battery to be replaced.

CRA CONCLUSIONS

All toothbrushes tested removed dental plaque. No automated toothbrush was substantially better than the conventional manual brush control in removing plaque. Toothbrushes making sonic & ultrasonic claims were not superior to either the manual brush control or to other automated toothbrushes in the study. Non-handicapped subjects indicated a high preference for the Advantage manual brush over all other brushes in the study because of superior control, convenience, ease of use, & low cost.

Automated Toothbrush Comparison
Statistical Report

Prepared by:

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Statistician
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July 23, 1998

EXECUTIVE SUMMARY

An evaluation of 6 toothbrushes was performed using 2 populations to determine if toothbrushes with sonic or ultrasonic capabilities reduce dental plaque more effectively than a manual or other automated toothbrushes. The Sensonic (Teledyne) and Sonicare (Optiva) toothbrushes claim sonic capabilities and the Ultrasonex (Sonex) claims ultrasonic capabilities. Control toothbrushes were the Interplak (Conair) and Ultra Plaque Remover (Braun), which are automated toothbrushes not claiming sonic or ultrasonic capabilities, and the Advantage (Oral-B) manual toothbrush. Population 1 consisted of 24 non-handicapped subjects, while Population 2 consisted of 24 institutionalized handicapped subjects. Non-handicapped subjects were included to represent the majority of the population, while handicapped subjects were included because they have been reported as having frequent problems with heavy plaque in their oral cavities due to lack of manual dexterity necessary for effective tooth brushing.

A Latin square design was used to allow each subject to use each of the 6 toothbrushes during the course of the evaluation. For Population 1, the design was balanced for crossover effects, meaning that every toothbrush directly followed every other toothbrush at some time during the evaluation. For Population 2, an incomplete Latin square design was used due to the necessity to randomize the handicapped subjects according to residence homes. As a result, each subject used each toothbrush, but all toothbrushes were *not* used during each period.

Subjects were randomly assigned to groups, and this randomization also specified treatment order. At the beginning of each period, plaque disclosing dye was administered and facial and lingual surfaces of test teeth were photographed using an intraoral camera. Test teeth were chosen as every other tooth present in the mouth. Subjects were instructed to use the assigned toothbrush for a total of 6 weeks, brushing twice a day for 2 minutes. Subjects were recalled twice during the 5th and 6th weeks to again stain and photograph the teeth. A two week washout period followed each 6 week recall, during which the subject brushed with the toothbrush he/she owned and used before the evaluation was initiated. All test periods followed these same procedures.

Plaque was quantified using image analysis software. The measurement used in the analyses was the ratio of the area of the tooth covered by plaque to the total tooth surface area, which is referred to as Percent Plaque Remaining after brushing.

The overall primary analysis showed that of the 6 toothbrushes evaluated, the Ultra Plaque Remover (Braun) left the least Percent Plaque Remaining on the teeth after brushing, followed by Sensonic (Teledyne), Advantage (Oral-B), Interplak (Conair), Ultrasonex (Sonex), and Sonicare (Optiva). Ultra Plaque Remover (Braun) and Sensonic (Teledyne) left significantly less plaque on the teeth after brushing than Sonicare (Optiva). Toothbrushes claiming sonic or ultrasonic capabilities did not reduce plaque more effectively than the manual toothbrush or other automated toothbrushes.

Survey information collected from non-handicapped subjects at the end of each period and at the end of the evaluation indicated that subjects liked the Advantage (Oral-B) more than any other toothbrush evaluated and they felt the Advantage (Oral-B) cleaned their teeth better than any other toothbrush evaluated. In addition, more subjects indicated they would purchase the Advantage (Oral-B) than any other toothbrush evaluated.

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1. INTRODUCTION

An evaluation with 2 populations was performed to examine the effects of 6 different toothbrushes on reducing dental plaque. The Sensonic (Teledyne) and Sonicare (Optiva) toothbrushes claim sonic capabilities and the Ultrasonex (Sonex) claims ultrasonic capabilities. Control toothbrushes were the Interplak (Conair) and Ultra Plaque Remover (Braun), which are automated toothbrushes not claiming sonic or ultrasonic capabilities, and the Advantage (Oral-B) manual toothbrush. The research question was: Do toothbrushes with sonic or ultrasonic capabilities reduce dental plaque more effectively than a manual or other automated toothbrushes?

Population 1 of the evaluation included a group of 24 non-handicapped adults age 21 to 59, with 13 females and 11 males. Five were left handed and 19 were right handed. Population 2 included a group of 24 institutionalized handicapped adults age 22 to 57, with 7 females and 17 males. Five were left handed, 15 were right handed, and dominant hand was unknown for 4 subjects in Population 2. Handicapped people have been reported as having frequent problems with heavy plaque in their oral cavities due to lack of manual dexterity necessary in tooth brushing. Since several of the test toothbrushes made specific claims of superior plaque removal capabilities, this was deemed an ideal test group because the toothbrush rather than the person would do the work and heavy plaque would be present. This report includes results from both populations of the evaluation.

2. EVALUATION DESIGN

The primary requirement in selecting a design for this evaluation was to allow every subject to use each of the 6 toothbrushes. The Latin square is a design which controls for 2 sources of variation, known as rows and columns, while applying a treatment to subjects. In this evaluation, the treatments were the 6 different toothbrushes. By designating columns in a Latin square as Periods, a crossover design for this evaluation was developed. Since the size of the Latin square is dependent on the number of treatments in the evaluation, a 6x6 Latin square was used. Subjects were assigned into treatment groups according to the descriptions below, and Groups were designated as the rows of the Latin square. This design allowed each group to use each toothbrush during the evaluation, fulfilling the primary requirement.

The complete Latin square is a very balanced design in several respects. Not only does each group use each toothbrush, as stated above, but each toothbrush is also used during each period. In addition, every toothbrush immediately precedes every other toothbrush. The Latin square designs used in each population of this evaluation were randomized, first by columns and then by rows.

2.1 Design for Population 1

Subjects in Population 1 of the evaluation received a professional scaling and polishing, then were asked to refrain from brushing for a period of 3 days. After the 3 days, plaque was disclosed with Trace 28, photographed using a Concept III intraoral camera, and quantified using Image-Pro Plus image analysis software. The plaque was quantified on the facial and lingual surfaces of every other tooth present. Subjects were ranked from greatest to least tendency to

accumulate plaque and divided into 4 sections with 6 subjects in each section. Each subject from the first section was randomly assigned to one of the 6 treatment groups. Next, each subject.from the second section was randomly assigned into one of the 6 treatment groups, and so on until each treatment group consisted of 4 subjects. Thus, treatment groups were stratified to include both heavier and lighter plaque formers. Table 1 gives the toothbrush assignments for each Group and Period in Population 1.

Table 1. Complete Latin square Design for Population 1

	Period 1	Period 2	Period 3	Period 4	Period 5	Period 6
Group 1	A	B	C	D	E	F
Group 2	B	D	F	A	C	E
Group 3	C	F	B	E	A	D
Group 4	D	A	E	B	F	C
Group 5	E	C	A	F	D	B
Group 6	F	E	D	C	B	A

2.2 Design for Population 2

Subjects in Population 2 of the evaluation received a professional scaling and polishing but did not complete a plaque accumulation classification due to the ethics and legalities of prohibiting oral hygiene in an institutionalized group. Subjects were instead clustered into treatment groups by their residence home assignment as a precautionary measure to prevent accidental use of the wrong toothbrush. This resulted in 4 groups with 4 to 9 subjects per group. The design used for Population 2 of the evaluation is shown in Table 2 below.

Table 2. Incomplete Latin square Design for Population 2

	Period 1	Period 2	Period 3	Period 4	Period 5	Period 6
Group 1	A	D	F	B	C	E
Group 2	F	C	E	A	B	D
Group 3	D	A	C	E	F	B
Group 4	B	E	A	C	D	F

Note that since there were not 6 groups, this is an incomplete Latin square design, meaning there are not the same number of rows and columns. As a result, not every toothbrush was used in each period, nor were treatments balanced for carryover effects. However, each group did use every toothbrush during the evaluation.

3. METHODS

After the 3 day plaque accumulation, subjects in Population 1 returned to their normal brushing habits for a 2 to 4 week plaque recovery period before starting Period 1 of the evaluation. For Population 1, manufacturers' printed instructions included in the toothbrush packaging were left for each subject to read on his/her own to mimic conditions present when toothbrushes are purchased commercially. However, as subjects in Population 2 of the evaluation received each toothbrush, they were instructed how to use it (turning it on, charging, etc.) In addition, a note was included with the Ultrasonex toothbrushes reminding caretakers that the toothbrush must be plugged in at all times.

Each subject was asked to brush twice a day for 2 minutes. Two minutes was chosen as the brushing time because 4 of the test toothbrushes specified this time and had built-in timers to facilitate the recommendation. One toothbrush had a 3 minute timer, and one did not have any timer. Because of this, 2 minute timers were purchased and issued to all evaluation subjects. Subjects were asked to disregard any built-in timers and instead use the issued timer to standardize the brushing time for all evaluation toothbrushes. Subjects were not supervised while brushing.

Each period of the evaluation consisted of an initial recall before the assigned toothbrush was issued to take home and use at the subject's customary brush times. Additional recalls occurred after 5 weeks and after 6 weeks of brushing with the assigned toothbrush. At each recall, the teeth of all test subjects were stained with Trace 28 to disclose accumulated plaque. Photographs of 12 to 14 predetermined teeth in each subject's oral cavity were then taken using a Concept III intraoral camera. Both the facial and lingual sides of each test tooth were photographed. Photographs were stored as digitized images on CD-ROM.

Digitized images were loaded into Image-Pro Plus image analysis software for plaque quantification. One of two researchers quantified the tooth surface covered by plaque and total tooth surface area for each image. Each researcher quantified images from both populations of the evaluation, and researchers were blinded to the toothbrush used as they quantified areas.

The same teeth were followed throughout the evaluation for each subject. Throughout the evaluation, subjects were not informed concerning the recall day, time of day, or designated test teeth. One investigator took all photographs during the course of the evaluation to eliminate possible variation due to multiple photographers.

Following the 6 week recall, the test toothbrush was collected, and a 2 week washout period followed, where the subject brushed with the toothbrush he/she owned and used before the evaluation was initiated. Washout periods are used to minimize or eliminate any carryover effects from the previous treatment. Periods 2 through 6 were completed following these same procedures, where all brushing was accomplished unsupervised at the subject's home.

4. MEASUREMENT VARIABLES

4.1 Response Variable

Percent Plaque Remaining for each tooth photographed was calculated as the ratio of the tooth surface covered by plaque to the total surface area of the tooth. Percent Plaque Remaining

measurements were averaged over the 5 week and 6 week recalls.

Percent Plaque Remaining measures were also averaged over all teeth for a particular subject. This created one value per subject for use in the overall and carryover analyses. For the separate analyses of the Population 1 and Population 2 data, Percent Plaque Remaining measures were averaged over all teeth in each area of the mouth for each subject. This created one value in each area of the mouth for each subject.

4.2 Fixed Factors

Fixed factors defined by the evaluation design and protocol included *Group*, *Period*, and the factor of most interest, *Toothbrush*. Using the tooth number, an *Area of the Mouth* factor was defined, which separated the mouth into every combination of upper/lower, facial/lingual, and anterior/premolar/molar. Other information was gathered from the subjects themselves, including *Gender* and *Dominant Hand*.

4.3 Covariates

Subject Age in years was one covariate. As subjects were recalled, the *Number of Days* they had been using that particular toothbrush was recorded. In addition, they were asked how much *Time* had elapsed *Since* their *Last Brushing* and *Last Flossing*. For more information regarding Time Since Last Flossing, see Appendix A (p.21). Time Since Last Flossing could not be measured accurately in hours, so flossing times were grouped for use in the covariate analysis as (a) 2 hours or less, (b) over 2 hours to 4 hours, (c) over 4 hours to 8 hours, or (d) over 8 hours. For the Population 2 data, Time Since Last Brushing values were also grouped using the same groupings as the flossing times.

The *Percent Plaque at Initial Recall* was also included as an additional covariate. This was the percent of plaque on the teeth at the initial recall of each period. In addition, for the Population 1 data only, a *Plaque Former Group* variable was included. These groups were based on the rankings of the overall tendencies to accumulate plaque (see section 2.1). Subjects were separated into 4 groups with 6 subjects in each group. Group 1 had the 6 lightest plaque formers, Group 4 had the 6 heaviest plaque formers, and the remaining groups were intermediate plaque formers.

5. STATISTICAL MODELS

The statistical software used for the analyses was PC SAS version 6.12. Proc GLM was used to model the data. Because of unequal sample sizes and the presence of covariates, least squares means were used for toothbrush comparisons. A Sidak adjusted α-value was used to adjust for all pairwise comparisons among toothbrushes. In all tables of results, levels of factors connected by vertical bars are not statistically different.

Proc MIXED was also used to model the data; however, due to the large number of factors and covariates, the models were unable to converge. For more information, see Appendix B (p.22).

6. ANALYSIS OF REPEAT DATA

Two researchers were used to quantify the digitized images of the stained teeth. Six images from each population of the evaluation were randomly chosen to serve as repeat images. These 6 images were interspersed among the images in each recall. Thus, during each recall of the evaluation, each of the 6 images was outlined 4 times by some combination of the 2 researchers. This provided a method of measuring the consistency of the 2 researchers over time. To measure the average error in the repeat images, a model was run with the Percent Plaque Remaining as the dependent variable. Fixed factors were the Image being quantified and the Researcher. Time was a covariate, where time represented each recall of each period. The Time by Researcher interaction was also included.

6.1 Estimate of Error in Measurements

All effects included in the model were significant with $p \leq 0.0001$. The root mean square error, which is a measure of the average error in measurements after accounting for all effects in the model, was 2.91. This indicates that on the average, there is an error of $\pm 2.91\%$ in the Percent Plaque Remaining measurements for each individual image.

6.2 Time Effect

The Time effect was also significant in this analysis. This indicates that as the evaluation progressed, the researchers quantified more plaque on the *exact same images*. Thus, an increasing Period effect in the analysis of the evaluation data could be due to actual increases in plaque over time, to the researcher time error, or some combination of the two. However, by including Period in the models and using least squares means in toothbrush comparisons, both sources of error are accounted for in the calculation of toothbrush means.

7. PRIMARY ANALYSIS OF EVALUATION DATA

The 2 populations of the evaluation were combined to produce an overall primary analysis. There was a possible total of 432 recalls for each population of the evaluation if every subject had attended all recalls. However, due to dropout and missing data, a total of 20 recalls (4.6%) were missing for Population 1. A total of 153 recalls (35.4%) were missing for Population 2 data.

The carryover effect was first determined to see if it should be included in the analysis. This effect was not significant (see section 7.2 below), so it was excluded from the primary analysis.

The model for the primary analysis included only the main fixed effects, which were: Toothbrush, Population (i.e., handicapped or non-handicapped), Period, Group nested within Population, and Patient nested within Group and Population. Covariates included in the initial model were Percent Plaque at Initial Recall, Time Since Last Brushing (grouped), and Number of Days Used. Terms that were not significant were subsequently dropped from the model to form the final model. Recall that all means reported in tables of results are least squares means.

7.1 Explanation of a Carryover Effect

A carryover effect refers to a lingering effect of one treatment which carries into the next treatment period. The purpose of including a washout period in a crossover study is to minimize or eliminate any carryover effects; however, sometimes the washout period is not long enough or other factors may cause the effect of a treatment to linger.

To assess the carryover effect, a new variable was defined as the Previous Toothbrush used. Table 3 illustrates how this variable was defined.

Table 3. Determining Previous Toothbrush Factor

	Prestudy	Period 1	Period 2	Period 3	Period 4	Period 5	Period 6
Toothbrush	G	A	B	C	D	E	F
Previous Toothbrush		G	A	B	C	D	E

In the table above, only toothbrushes A through F were treatment toothbrushes included in the evaluation. Toothbrush G is a code indicating the subject's original toothbrush used before the evaluation began and during the washout periods. Therefore, for every subject, the Previous Toothbrush used for period 1 will be Toothbrush G.

7.2 Carryover Effect for Overall Analysis

A statistical model was run including only Population, Period, Toothbrush, and Previous Toothbrush as factors and Percent Plaque Remaining as the response variable. Only the initial recall for each period was included, since it was the measurement taken most immediately after each washout period. Percent Plaque at Initial Recall could not be used as a covariate in this particular analysis since it was used as the response variable.

Using the model specified above, the Previous Toothbrush effect was not significant with p=0.9882. It appears that the washout period of 2 weeks did a sufficient job of eliminating any lagging effects of a previously used toothbrush. As a result, the Previous Toothbrush factor was not included in other models in the primary analysis.

7.3 Results of Primary Analysis

The Population, Period, Toothbrush, and Patient effects were significant. Group was not significant, nor were any of the covariates. However, the Percent Plaque at Initial Recall covariate was left in the model since least squares means adjust for the covariate. The overall Toothbrush effect was significant with p=0.0031. Table 4 lists the mean for each toothbrush, sorted from least plaque remaining to most plaque remaining.

Table 4. Primary Analysis: Overall Mean Percent Plaque
Remaining for Each Test Toothbrush Used by Both Non-
handicapped and Handicapped Subjects

Toothbrush	Mean
Ultra PR (Braun)	30.10
Sensonic (Teledyne)	30.86
Advantage (Oral-B)	30.96
Interplak (Conair)	32.09
Ultrasonex (Sonex)	
Sonicare (Optiva)	33.59

7.3.1 Major Findings of Primary Analysis

The following are the major findings from the overall primary analysis of toothbrushes:

- Ultra PR (Braun) left the least plaque remaining, but is not significantly different from the next 4 toothbrushes.
- Ultra PR (Braun) and Sensonic (Teledyne) had significantly less plaque remaining than Sonicare (Optiva).
- Interplak (Conair), Ultrasonex (Sonex) and Sonicare (Optiva) had more plaque remaining than the Advantage (Oral-B) manual toothbrush, but the differences were not significant.

8. ANALYSIS OF POPULATION 1 DATA

In the primary analysis, the Population factor was highly significant with $p \leq 0.0001$, indicating that Percent Plaque Remaining differed for handicapped and non-handicapped subjects. Therefore, the 2 populations of the evaluation were analyzed separately to see if different patterns would appear for the 2 sets of subjects. This also allowed interactions among factors to be examined more closely.

As in the primary analysis, the carryover effect was first assessed to see if it should be included in the analysis. This effect was not significant (see section 8.1 below), so it was excluded from the primary analysis.

The model for the Population 1 analysis included covariates, interactions, and main effects. Terms that were not significant were subsequently dropped from the model to form the final model, which included only Percent Plaque at Initial Recall covariate, Toothbrush, Period, Area of the Mouth, Subject, and the Toothbrush by Area of the Mouth interaction. Recall that all means reported in tables of results are least squares means.

8.1 Carryover Effect for Population 1 Data

A statistical model was run including only Period, Toothbrush, and Previous Toothbrush as factors and Percent Plaque Remaining as the response variable. Only the initial recall for each period was included, since it was the measurement taken most immediately after each washout

period. Percent Plaque at Initial Recall could not be used as a covariate in this particular analysis since it was used as the response variable.

Using the model specified above, the Previous Toothbrush effect was not significant with p=0.9992. It appears that the washout period of 2 weeks did a sufficient job of eliminating any lagging effects of a previously used toothbrush. As a result, the Previous Toothbrush factor was not included in other models in the Population 1 analysis.

8.2 Toothbrush by Area of the Mouth Interaction

Analyzing the Population 1 data only, the Toothbrush by Area of the Mouth interaction was significant with p=0.0012. This significance means that the differences among the toothbrushes depend on the Area of the Mouth. Table 5 shows the means of each toothbrush in each area of the mouth. Area of the Mouth has been coded to a 3-letter abbreviation according to the following legend:

Area of Mouth:			
First letter	u = upper	l = lower	
Second letter	f = facial	l = lingual	
Third letter	a = anterior	p = premolar	m = molar

Toothbrushes are color coded according to the legend to the left of the table. Means are listed from least plaque remaining to most plaque remaining within each area of the mouth.

Table 5. Population 1 Data: Mean Percent Plaque Remaining for Toothbrush by Area of the Mouth Interaction

	lfa	lfm	lfp	lla	llm	llp
	...	15.56	...	17.05	23.21	23.03
	15.10	19.43	15.11	20.15	23.27	...
	15.43	19.69	16.04	...	23.75	25.23
	16.20	...	16.29	23.14	...	26.33
	16.62	20.19	17.16	24.83	25.17	27.69
	19.23	23.17	18.36	28.55	26.53	29.23

Legend
Advantage (Oral-B)
Interplak (Conair)
Sensonic (Teledyne)
Sonicare (Optiva)
Ultra PR (Braun)

	ufa	ufm	ufp	ula	ulm	ulp
	13.88	19.40	14.82	15.25	16.30	14.96
	14.04	23.77	...	16.39	...	...
	14.74	25.50	15.32	...	17.55	15.89
	15.24	...	15.75	17.97	18.10	16.09
	...	27.26	15.87	19.49	18.57	16.48
	16.31	30.17	16.54	19.87	20.21	16.53

8.2.1 Major Findings

The following are the major findings from the Toothbrush by Area of the Mouth interaction for

the Population 1 data:
- Differences among toothbrushes were seen in only 4 of the 12 areas of the mouth. These were: lower facial molars, lower lingual anteriors, lower lingual premolars, and upper facial molars.
- In all 4 of these areas, Ultra PR (Braun) performed the best of the 6 toothbrushes.

Percent Plaque Remaining in each of the Areas of the Mouth where significant differences were found can be summarized as follows.

Lower facial molars
- Ultra PR (Braun) had significantly less plaque remaining than Sonicare (Optiva).
- Ultrasonex (Sonex), Sensonic (Teledyne), and Sonicare (Optiva) had more plaque remaining than the Advantage (Oral-B) manual toothbrush, but the differences were not significant.

Lower lingual anteriors
- Ultra PR (Braun) had significantly less plaque remaining than Interplak (Conair), Advantage (Oral-B) and Sonicare (Optiva).
- Sensonic (Teledyne), Ultrasonex (Sonex), and Interplak (Conair) had significantly less plaque remaining than Sonicare (Optiva).
- Only Sonicare (Optiva) had more plaque remaining than the Advantage (Oral-B) manual toothbrush, but the difference was not significant.

Lower lingual premolars
- Ultra PR (Braun) had significantly less plaque remaining than Interplak (Conair).
- Sensonic (Teledyne), Sonicare (Optiva), and Interplak (Conair) had more plaque remaining than the Advantage (Oral-B) manual toothbrush, but the differences were not significant.

Upper facial molars
- Ultra PR (Braun) had significantly less plaque remaining than Sonicare (Optiva), Ultrasonex (Sonex), Advantage (Oral-B), and Sensonic (Teledyne).
- Interplak (Conair) had significantly less plaque remaining than Sensonic (Teledyne).
- Only Sensonic (Teledyne) had more plaque remaining than the Advantage (Oral-B) manual toothbrush, but the difference was not significant.

8.3 Significance of Other Terms in Model

A number of additional covariates, interactions, and main effects were included in the original model but dropped due to non-significance. These were:
Covariates
Number of Days toothbrush used (p=0.2394)
Time Since Last Brushing (p=0.4351)
Time Since Last Flossing (grouped as outlined in section 4.3) (p=0.3896)

Subject Age (p=0.2879)

Interactions
      Toothbrush by Gender (p=0.9288)
      Toothbrush by Dominant Hand (p=0.7183)
      Toothbrush by Plaque Former Group (p=0.9608)
      Dominant Hand by Area of the Mouth (p=0.9689)
      Area of the Mouth by Plaque Former Group (p=0.9999)

Main Effects
      Gender (p=0.7342)
      Dominant Hand (p=0.4978)
      Group (p=0.1575)
      Plaque Former Group (p=0.9326)

8.4 Overall Averages for Toothbrushes for Population 1 Data

Using Population 1 data only, an analysis was performed to calculate the overall mean Percent Plaque Remaining for each toothbrush. The significant interaction of Toothbrush by Area of the Mouth remained in the model and least squares means were calculated to account for this term. Table 6 shows the mean for each toothbrush, sorted from least plaque remaining to most plaque remaining.

Table 6. Population 1 Data: Mean Percent Plaque Remaining for Each Test Toothbrush Used by Non-handicapped Subjects Only

Toothbrush	Mean
Ultra PR (Braun)	17.33
Ultrasonex (Sonex)	18.
Interplak (Conair)	19.33
Sensonic (Teledyne)	19.36
Advantage (Oral-B)	20.09
Sonicare (Optiva)	21.31

8.4.1 Major Findings

The following are the major findings from the overall analysis of the Population 1 data:
- Overall, the Ultra PR (Braun) left the least plaque remaining, and Sonicare (Optiva) left the most plaque remaining.
- Ultra PR (Braun) left significantly less plaque remaining than all other toothbrushes.
- Ultrasonex (Sonex), Interplak (Conair), and Sensonic (Teledyne) left significantly less plaque remaining than Sonicare (Optiva).
- Only Sonicare (Optiva) had more plaque remaining than the Advantage (Oral-B) manual toothbrush, but the difference was not significant.

9. ANALYSIS OF POPULATION 2 DATA

As in the primary analysis, the carryover effect was first assessed to see if it should be included in the analysis. This effect was not significant (see section 9.1 below), so it was excluded from the primary analysis.

The model for the Population 2 analysis included covariates, interactions, and main effects. Recall that in Population 2 of the evaluation, an assessment of plaque accumulation for each subject was not made due to concern about asking handicapped subjects to refrain from brushing for 3 days. Thus, the Plaque Former Group variable was not included in this analysis. In addition, subjects in Population 2 did not use floss due to safety concerns of care personnel, so Time Since Last Flossing was excluded as a covariate.

In Population 2, all left-handed subjects were male. Therefore, all combinations of Gender and Dominant Hand were not represented. An analysis showed that the effect of Dominant Hand was not significant after the effect of Gender had been assessed. Thus, only the Gender factor was included in the analysis and the Dominant Hand factor was excluded as a non-significant factor.

Terms that were not significant were dropped from the model to form the final model, which included only Percent Plaque at Initial Recall covariate, Toothbrush, Period, Area of the Mouth, and Subject. Recall that all means reported in tables of results are least squares means.

9.1 Carryover Effect for Population 2 Data

The carryover effect for the Population 2 data was calculated similarly to the Population 1 data. A statistical model was run including only Period, Toothbrush, and Previous Toothbrush as factors and Percent Plaque Remaining as the response variable. Only the initial recall for each period was included, since it was the measurement taken most immediately after the washout period. Percent Plaque at Initial Recall could not be used as a covariate in this particular analysis since it was used as the response variable.

Using the model specified above, the Previous Toothbrush factor was not significant with $p=0.9552$. It appears that the washout period of 2 weeks did a sufficient job of eliminating any lagging effects of a previously used toothbrush. Note that since an incomplete Latin square was used for Population 2, the design was not balanced for carryover effects. However, only the initial recall data, before the subject ever used the treatment toothbrush, were used in this analysis. Thus, lack of balance would only have been a concern if the carryover effect had been significant. Since the carryover effect was highly non-significant, the Previous Toothbrush factor was not included in other models in the Population 2 analysis.

9.2 Significance of Other Terms in Model

A number of additional covariates, interactions, and main effects were included in the original model but dropped due to non-significance. These were:

Covariates
>   Number of Days toothbrush used (p=0.7907)
>   Time Since Last Brushing (grouped as outlined in section 4.3) (p=0.3727)
>   Subject Age (p=0.8808)

Interactions
>   Toothbrush by Gender (p=0.6986)
>   Toothbrush by Area of the Mouth (p=0.9356)
>   Gender by Area of the Mouth (p=0.9351)

Main Effects
>   Gender (p=0.0853)
>   Group (p=0.5206)

9.3 Overall Averages for Toothbrushes for Population 2 Data

Using Population 2 data only, an analysis was performed to calculate the overall mean Percent Plaque Remaining for each toothbrush. No interactions remained in the model but least squares means were calculated to adjust for covariates. Table 7 shows the mean for each toothbrush, sorted from least plaque remaining to most plaque remaining.

Table 7. Population 2 Data: Mean Percent Plaque Remaining for Each
Test Toothbrush Used by Handicapped Subjects Only

Toothbrush	Mean
Advantage (Oral-B)	41.90
Ultra PR (Braun)	43.41
. :	. . . .
Sensonic (Teledyne)	43.88
Interplak (Conair)	44.40
Sonicare (Optiva)	46.91

9.3.1 Major Findings

The following are the major findings from the overall analysis of the Population 2 data:
*   Advantage (Oral-B) left the least plaque remaining, and Sonicare (Optiva) left the most plaque remaining.
*   Advantage (Oral-B) left significantly less plaque remaining than Sonicare (Optiva).
*   There were no differences among any of the other toothbrushes.

10. SURVEY RESULTS

Two types of survey data were collected from non-handicapped subjects only. First, information regarding likes, dislikes, and purchase attitude toward each toothbrush was collected following the 6 week recall of each period. Second, a more detailed final survey was completed at the conclusion of the evaluation, after all 6 toothbrushes had been used. Subjects were allowed to visually and physically examine all 6 toothbrushes simultaneously as they completed the final survey.

10.1 Survey Completed at the End of Each Period

Following are results from the surveys following use of each toothbrush. Recall that only non-handicapped subjects completed these surveys.

10.1.1 Likes and Dislikes

Table 8 lists subjects' most common likes and dislikes of each toothbrush. Most common is defined as those comments with the 2 highest frequencies of occurrence. Frequencies are listed in parentheses following each comment. For a complete listing of all comments see Appendix C (pp.23-25).

Table 8. Most Common Likes and Dislikes of each Toothbrush Compiled from Surveys Conducted After each Period

Toothbrush	Likes		Dislikes	
Advantage (Oral-B)	Ease of use (comfort, control, convenience)	(11)	Bristles too soft	(4)
			Brush head	(3)
	Handle & grip	(9)	Handle & grip	(3)
Interplak (Conair)	Felt cleaned teeth well	(11)	Stalls	(7)
	Timer	(6)	Taste (oil, metallic, bad)	(7)
	Access	(6)		
Sensonic (Teledyne)	Felt cleaned teeth well	(7)	Vibration	(8)
	Timer	(7)	Handle & grip	(4)
	Handle & grip	(7)		
Sonicare (Optiva)	Timer with Quad Pacer	(10)	Felt did not clean teeth well	(9)
	Felt cleaned teeth well	(7)	Brush head	(8)
Ultra PR (Braun)	Small brush head	(15)	Felt did not clean teeth well	(5)
	Access	(13)	Small head	(4)
Plaque Control (Panasonic)	Use like a manual brush	(6)	Large brush head	(9)
	Felt cleaned teeth well	(6)	No on/off switch	(7)

10.1.2 Purchase Attitude

Table 9 lists the responses to the question "Would you buy this brush?" for each toothbrush. Toothbrushes are listed from most *yes* responses to fewest *yes* responses.

Table 9. Responses to "Would you buy this brush?" from Surveys Taken After Each Use-Period

Toothbrush	Yes	No	Maybe	No Response	Did not use	Total
Advantage (Oral-B)	22	1	0	1	0	24
Ultra PR (Braun)	13	10	0	0	1	24
Interplak (Conair)	10	14	0	0	0	24
Sensonic (Teledyne)	8	14	0	1	1	24
Sonicare (Optiva)	5	17	0	0	2	24

Twenty two of 23 subjects indicated they would purchase the Advantage (Oral-B). Slightly over half of the subjects indicated they would purchase the Ultra PR (Braun), while slightly less than one half of the subjects indicated they would purchase the Interplak (Conair).

No subject indicated desire to purchase Ultrasonex (Sonex). For a complete listing of why subjects would or would not purchase, see Appendix D (pp.26-27).

10.2 Final Survey Completed at the End of the Evaluation

Each subject in Population 1 also completed a final survey, which was administered upon completion of the entire evaluation. This final survey provided the opportunity to compare all 6 toothbrushes. Table 10 lists the responses to selected questions from this survey. Numbers in the table are the number of subjects agreeing with the statement. Toothbrushes are listed in order of most "likes" to least "likes". For complete final survey results, see Appendix E (p.28).

Table 10. Responses to Selected Questions from the Survey Conducted at the End of the One-Year Evaluation

Toothbrush	Subject Likes Toothbrush	Subject Dislikes Toothbrush
Advantage (Oral-B)	18	3
Ultra PR (Braun)	15	5
Interplak (Conair)	11	12
Sensonic (Teledyne)	8	10
Sonicare (Optiva)	5	14

The Advantage (Oral-B) and Ultra PR (Braun) were liked by the most subjects (18 and 15, respectively). The Ultrasonex (Sonex) was disliked by 19 subjects, more than any other toothbrush.

10.2.1 Toothbrush Rankings

Subjects were asked to rank the 6 toothbrushes according to: (a) most favorite to least favorite, and (b) how well they felt the toothbrush cleaned their teeth. A lower number indicates a more favorable toothbrush. Ranks were averaged across subjects to produce the average ranks shown in Table 11.

The toothbrushes ranked the same for the 2 different questions. Advantage (Oral-B) was most favored of the 6 toothbrushes for both preference and cleaning. Ultra PR (Braun) ranked second to the Advantage (Oral-B), followed by Sensonic (Teledyne), Interplak (Conair), Sonicare (Optiva), and Ultrasonex (Sonex).

Table 11. Average Ranks of Toothbrushes from the Survey Conducted at the End of the One-Year Evaluation (Lower rank indicates more favorable toothbrush)

Toothbrush	Favorite toothbrush	How well toothbrush cleaned
Advantage (Oral-B)	2.5	2.3
Ultra PR (Braun)	2.7	2.5
Sensonic (Teledyne)	3.3	3.2
Interplak (Conair)	3.7	3.7
Sonicare (Optiva)	4.1	4.2

11. CONCLUSIONS

The overall primary analysis of the Percent Plaque Remaining showed the toothbrushes ranked as follows: Ultra PR (Braun), Sensonic (Teledyne), Advantage (Oral-B), Interplak (Conair), Ultrasonex (Sonex), and Sonicare (Optiva). The Ultra PR (Braun) and Sensonic (Teledyne) left significantly less plaque remaining than Sonicare (Optiva). There were no statistical differences among the other toothbrushes.

For non-handicapped users, significant differences among toothbrushes were seen in 4 areas of the mouth (lower facial molars, lower lingual anteriors, lower lingual premolars, and upper facial molars), with Ultra PR (Braun) leaving least plaque remaining in all 4 of those areas. For handicapped users, the Advantage (Oral-B) had significantly less plaque remaining than Sonicare (Optiva). There were no statistical differences among the other toothbrushes.

Surveys conducted after each test period and at the completion of the entire study gave additional insights about the toothbrushes from the users. More subjects indicated they would purchase the Advantage (Oral-B) than any other toothbrush evaluated. The Advantage (Oral-B) was ranked as the favorite toothbrush evaluated, and subjects also felt it cleaned their teeth best of the 6 toothbrushes evaluated.

Toothbrushes claiming sonic or ultrasonic capability did not reduce plaque more effectively than the manual toothbrush or other automated toothbrushes.

Appendix

Appendix A. Explanation of *Time Since Last Flossing* Measure

Subjects in the evaluation were asked to continue their normal oral hygiene habits throughout the course of the evaluation in an effort to make the results as true to life as possible. Since flossing was considered a normal oral hygiene habit, subjects were not prohibited from flossing for this evaluation. However, flossing data were only collected from the non-handicapped subjects since the handicapped subjects in this evaluation were not allowed to use floss due to safety concerns of care personnel.

The chart below lists the number and percentage of individual subject recalls which fall into the specified categories of Time Since Last Flossing for each toothbrush. Note that with 24 subjects each using 6 toothbrushes and 3 recalls per toothbrush, there was a possible maximum of 432 individual subject recalls. However, due to dropout and missing data, only a total of 410 individual subject recalls were counted.

Toothbrush	0 to 6 hours	Over 6 to 24 hours	Over 24 hours	No time given	Total
Advantage	2 2.86%	20 28.57%	31 44.29%	17 24.29%	70
Interplak	5 6.94%	12 16.67%	36 50.00%	19 26.39%	72
Sensonic	5 7.69%	16 24.62%	29 44.62%	15 23.08%	65
Sonicare	6 9.09%	24 36.36%	20 30.30%	16 24.24%	66
Ultra PR	6 8.70%	17 24.64%	28 40.58%	18 26.09%	69
					68

Note that for purposes of analysis, the recalls with no flossing time given were grouped with the category of longest Time Since Last Flossing.

Appendix B. Analysis using Proc MIXED

Multiple attempts were made to model the data using Proc MIXED; however, due to the large number of factors and covariates, the models were unable to converge. The suggestion was made to use the final model from Proc GLM to estimate means in Proc MIXED. Results for the primary analysis are shown in the following tables.

Mean Percent Plaque Remaining for each Toothbrush

Means from Proc GLM		Means from Proc MIXED	
Ultra PR (Braun)	30.10	Ultra PR (Braun)	29.88
Sensonic (Teledyne)	30.86	Sensonic (Teledyne)	30.59
Advantage (Oral-B)	30.96	Advantage (Oral-B)	30.80
Interplak (Conair)	32.09	Ultrasonex (Sonex)	31.1
Ultrasonex (Sonex)	32.3	Interplak (Conair)	31.97
Sonicare (Optiva)	33.59	Sonicare (Optiva)	33.39

The means from the two procedures were similar, although the Proc MIXED means generally tend to be slightly lower than the means from Proc GLM. The Interplak (Conair) and Ultrasonex (Sonex) exchanged rankings; however, the statistical groupings from both procedures are identical.

Appendix C. Responses to the Survey Conducted at the End of Each Test Period - Likes and Dislikes of each Toothbrush (Frequency of comment in parentheses)

	Likes		Dislikes	
Advantage (Oral-B)	Ease of use (comfort, control, convenience)	(11)	Nothing	(7)
	Handle & grip	(9)	Bristles too soft	(4)
	Access	(8)	Brush head	(3)
	Brush head	(5)	Handle & grip	(3)
	Felt cleaned teeth well	(5)	Felt did not clean teeth well	(2)
	Bristles (size, shape, stiffness)	(4)	Not electric	(2)
	Size	(3)	Bristles wore out quickly	(1)
	Indicator bristles	(2)	Indicator bristles lasted too long	(1)
	Light weight	(2)	Expensive	(1)
	No vibrations	(2)	Contributes to carpal tunnel syndrome	(1)
	Everything, good overall	(2)	White (opaque) bristles hid paste, required	
	Did not require charging	(1)	careful cleaning	(1)
	Color combination	(1)		
	No splatter mess	(1)		
	Quiet	(1)		
	No instructions	(1)		
	Does not stall with pressure	(1)		
	Long bristles on tip of head	(1)		
Interplak (Conair)	Felt cleaned teeth well	(11)	Stalls	(7)
	Timer	(6)	Taste (oil, metallic, bad)	(7)
	Access	(6)	Did not hold charge well	(5)
	Holds charge well	(4)	Sound	(5)
	Brush head cover	(4)	Aggressive	(4)
	Easy to use	(3)	Large size	(4)
	Nothing	(3)	Poor Access	(4)
	Bristles (size, shape, stiffness)	(3)	Felt did not clean teeth well	(3)
	Charging system	(2)	Nothing	(3)
	Head size	(2)	Causes sensitivity	(2)
	Handle & grip	(2)	Tufts too far apart	(2)
	Disassembles for travel	(1)	Head would not fit in holder with cover on	(1)
	Easy to clean	(1)	Bristles started falling out	(1)
	On/off switch	(1)	No low charge warning	(1)
	Massages gums	(1)	Did not hold tooth paste well	(1)
	Gentle	(1)	Brush head gets hot	(1)
	Good tongue cleaner	(1)	Bristles too long	(1)
	Different head sizes available	(1)	Handle & grip	(1)
	Ease of head attachment	(1)	Large head	(1)
	Size of base	(1)	Weight	(1)
	Green LED shows charging	(1)		

Appendix C. (Continued)

	Likes		Dislikes	
Sensonic (Teledyne)	Felt cleaned teeth well	(7)	Vibration	(8)
	Timer	(7)	Handle & grip	(4)
	Handle & grip	(7)	Difficulty keeping head clean	(3)
	Brush head	(6)	Felt did not clean teeth well	(3)
	Holds charge well	(5)	Poor access	(2)
	Easy to use	(5)	On/off switch	(2)
	Flat electrical plug	(4)	Brush broke down	(2)
	Access	(3)	Cost	(2)
	Light weight	(2)	Bristles wear out quickly	(1)
	Charge level indicator lights	(2)	Vibration of handle	(1)
	On/off switch	(2)	Caused sensitivity	(1)
	Nothing	(1)	Sound	(1)
	Sound	(1)	No 30 second indicator with timer	(1)
	Bristles (size, shape, stiffness)	(1)	Size	(1)
	Brush head holder	(1)	No brush head cover	(1)
	Easy to clean	(1)	Electrical plug too big	(1)
	Color scheme	(1)	Unstable base unit	(1)
	Ease of head attachment / detachment	(1)	Insufficient instructions	(1)
	Speed of movement	(1)	No charging indicator light	(1)
	Gentle	(1)	Neck felt weak	(1)
	Base unit	(1)		
	Fast recharging time	(1)		
	No mess	(1)		
Sonicare (Optiva)	Timer with Quad Pacer	(10)	Felt did not clean teeth well	(9)
	Felt cleaned teeth well	(7)	Brush head	(8)
	Holds charge well	(6)	Splatter mess	(7)
	Movement of bristles	(5)	Vibration	(5)
	Small base unit	(4)	Plastic piece behind bristles	(5)
	Brush head cover	(3)	Sound	(4)
	Easy to use	(2)	Access	(3)
	Nothing	(2)	Aggressive	(3)
	On/off switch	(2)	Difficult to clean	(2)
	Size	(2)	Caused sensitivity	(2)
	Easy to clean	(1)	No low power band included	(2)
	Color scheme	(1)	Bristles wear out quickly	(1)
	Bristles (size, shape, stiffness)	(1)	Large size	(1)
	Brush head	(1)	Bristles (size, shape, stiffness)	(1)
	Gentle	(1)	No low charge warning	(1)
	Brush can stay on charger	(1)	Heavy base unit	(1)
	Sound	(1)	Causes sensation	(1)
			Cost	(1)

Appendix C. (Continued)

	Likes		Dislikes	
Ultra PR (Braun)	Small brush head	(15)	Felt did not clean teeth well	(5)
	Access	(13)	Nothing	(4)
	Felt cleaned teeth well	(7)	Small head	(4)
	Timer	(6)	Bristles wear out quickly	(3)
	Brush head holder	(4)	Did not hold charge well	(3)
	Holds charge well	(4)	Off button	(2)
	Easy to use	(4)	Damaged gums	(2)
	Size	(4)	Small head doesn't hold enough toothpaste	(2)
	Vibration	(2)	Cheap feeling	(1)
	Lightweight	(2)	Grip	(1)
	Design	(2)	No low charge indicator	(1)
	Color scheme	(1)	Move brush slowly around mouth	(1)
	Quiet	(1)	Aggressive	(1)
	Indicator bristles	(1)	Caused sensitivity	(1)
	Long neck	(1)	No brush head cover	(1)
	Gentle on gums	(1)	No 30 second indicator with timer	(1)
	On/off switch	(1)	Difficult to clean brush head holder	(1)
	Rotational motion	(1)	Taste (oil)	(1)
	Bristles (size, shape, stiffness)	(1)	Indicator bristle dye ran down brush	(1)
	No gagging	(1)	Difficult to clean brush head	(1)
			Vibration	(1)
			Indicator bristles wear out quickly	(1)
			Bristles (size, shape, stiffness)	(1)
Ultraspeed (Oral-B)	Use like a manual brush	(6)	Large brush head	(9)
	Felt cleaned teeth well	(6)	No on/off switch	(7)
	Small base unit	(5)	Sound	(6)
	Handle & grip	(4)	Does not hold charge	(6)
	No vibrations	(2)	Handle & grip	(5)
	Bristles (size, shape, stiffness)	(2)	Access	(3)
	Improved gums	(2)	Felt did not clean teeth well	(3)
	Timer	(2)	Uncertain if brush is working	(3)
	Easy to use	(1)	Turns on when accidentally bumped off base unit	(2)
	Nothing	(1)		
	Light weight	(1)	Must keep base unit plugged in to maintain charge	(2)
	Neck of brush	(1)		
			Cannot return brush to base unit until timer shuts off	(2)
			Long recharge time	(2)
			Not suited for travel	(2)
			Timer	(2)
			Bristles (size, shape, stiffness)	(2)
			Caused sore gums	(1)
			Cannot stand up by itself	(1)
			Bristles wear out quickly	(1)
			Weight	(1)

Appendix D. Responses to the Survey Conducted at the End of Each Test Period - Reasons Subjects Would or Would Not Purchase Toothbrush (Frequency of comment in parentheses)

	Why would purchase		Why would not purchase	
Advantage (Oral-B)	Ease of use (comfort, control, convenience)	(10)	Cost	(1)
	Cost	(8)	Handle & grip	(1)
	Felt cleaned teeth well	(5)		
	Design, color scheme	(2)		
	Access	(2)		
	Good, for a manual brush	(2)		
	Manual brush	(1)		
	Bristles	(1)		
	Handle & grip	(1)		
	Size	(1)		
Interplak (Conair)	Felt cleaned teeth well	(7)	Cost	(5)
	Cost	(2)	Felt did not clean teeth well	(3)
	Gentle	(1)	Sound	(2)
	Liked brush	(1)	Did not like brush	(2)
			Prefers manual brush	(1)
			Stalls	(1)
Sensonic (Teledyne)	Felt cleaned teeth well	(2)	Cost	(6)
	Ease of use	(2)	Did not like brush	(2)
	Cost	(1)	Felt did not clean teeth well	(2)
	Appearance	(1)	Vibration	(2)
			Poor access	(1)
			On/off switch	(1)
			Caused sensitivity	(1)
			Prefers manual brush	(1)
Sonicare (Optiva)	Felt cleaned teeth well	(3)	Cost	(9)
	On/off switch	(1)	Felt did not clean teeth well	(5)
	Cost	(1)	Vibration	(3)
	Holds charge well	(1)	Did not like brush	(3)
			Large brush head	(2)
			Splatter mess	(2)
			Causes sensation	(1)
			Poor access	(1)
			Bristles wear out quickly	(1)
			Plastic piece behind bristles	(1)
			Difficult to clean	(1)

Appendix D. (Continued)

	Why would purchase		Why would not purchase	
Ultra PR (Braun)	Felt cleaned teeth well	(5)	Felt did not clean teeth well	(4)
	Cost	(2)	Cost	(4)
	Easy to use	(2)	Prefer manual brush	(2)
	Access	(2)	Aggressive	(1)
	Comfortable	(2)	Damaged gums	(1)
	Easy to clean	(1)	Causes sensitivity	(1)
	Vibration does not irritate	(1)	Small brush head	(1)
	Swirling motion foamed tooth paste	(1)	Uncomfortable	(1)
	Promotes brushing for children	(1)		
	Small brush head	(1)		
	Timer	(1)		
	Like brush	(1)		
	Design	(1)		
(Braun)			Felt did not clean teeth well, or better than manual brush	(6)
			Cost	(6)
			Need to understand brush better first	(5)
			Does not hold charge	(4)
			Brush head	(3)
			Prefers manual brush	(3)
			Size	(2)
			Handle & grip	(2)
			Similar to inexpensive manual brush	(1)
			Access	(1)
			Timer	(1)
			Turns on when accidentally bumped off base unit	(1)
			Sound	(1)
			No on/off switch	(1)
			Not suited for travel	(1)
			Cannot stand up by itself	(1)
			Annoying	(1)

Appendix E. Responses to the Survey Conducted at the End of the One-Year Evaluation – Complete Final Survey Results (Numbers in table are frequencies of agreement)

Toothbrush	Subject Likes Toothbrush	Subject Dislikes Toothbrush	Uncomfortably Heavy	Uncomfortably Lightweight	Uncomfortably Large	Uncomfortably Small	Uncomfortably Large Brush Head	Uncomfortably Small Brush Head
Advantage (Oral-B)	18	3	0	0	0	0	0	0
Interplak (Conair)	10	12	8	0	9	0	9	1
Sensonic (Teledyne)	8	10	9	0	10	0	2	0
Sonicare (Optiva)	4	14	18	0	16	0	9	0
Ultra PR (Braun)	15	4	2	0	1	2	0	7

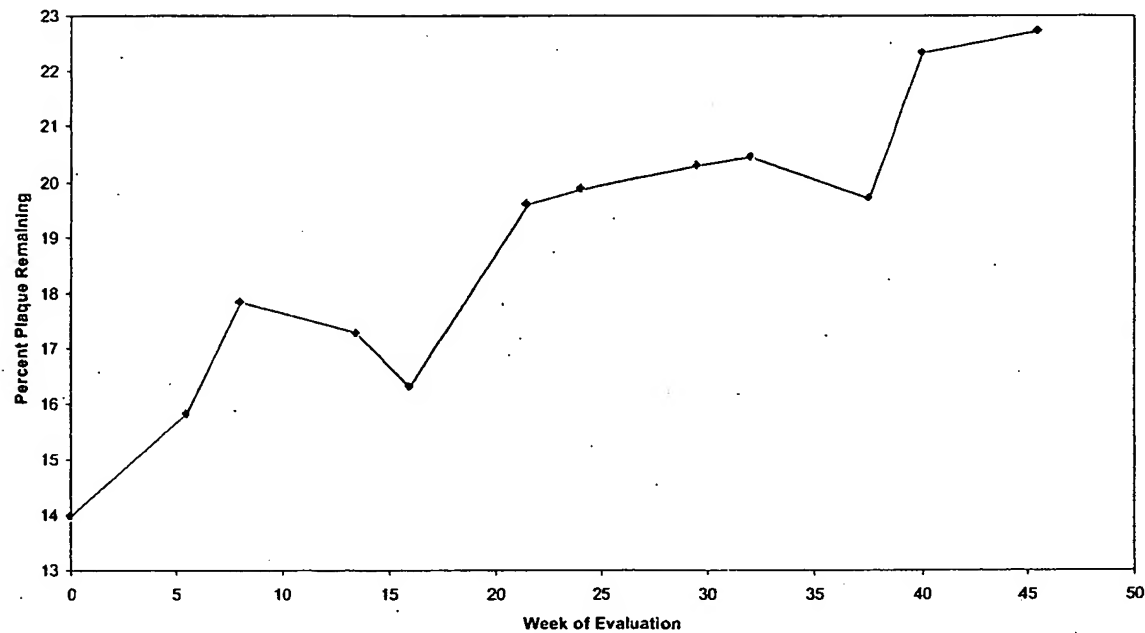| Toothbrush	Comfortable Grip	Uncomfortable Grip	Liked On/Off Control	Disliked On/Off Control	Disliked Vibration/ Movement	Liked Vibration/ Movement	Awkward Recharging Base	Convenient Recharging Base
Advantage (Oral-B)	14	1	5	0	0	4	0	2
Interplak (Conair)	10	4	12	2	9	8	5	9
Sensonic (Teledyne)	10	7	10	4	13	5	8	6
Sonicare (Optiva)	2	11	9	2	14	3	5	8
Ultra PR (Braun)	9	5	6	9	4	14	7	9

Toothbrush	Difficultly Charging	Mechanical Difficulty	Other Features Disliked	Other Features Liked	Annoying Sound	Poorly Balanced	Uncomfortable Length
Advantage (Oral-B)	0	0	2	4	0	0	0
Interplak (Conair)	5	7	7	5	17	2	6
Sensonic (Teledyne)	4	4	4	6	13	4	9
Sonicare (Optiva)	1	0	6	5	12	13	4
Ultra PR (Braun)	2	0	2	7	10	0	0

Toothbrush	Average rank* of how well brush cleaned	Average rank* of favorite toothbrush
Advantage (Oral-B)	2.3	2.5
Ultra PR (Braun)	2.5	2.7
Sensonic (Teledyne)	3.2	3.3
Interplak (Conair)	3.7	3.7
Sonicare (Optiva)	4.2	4.1

*Lower rank indicates more favorable toothbrush

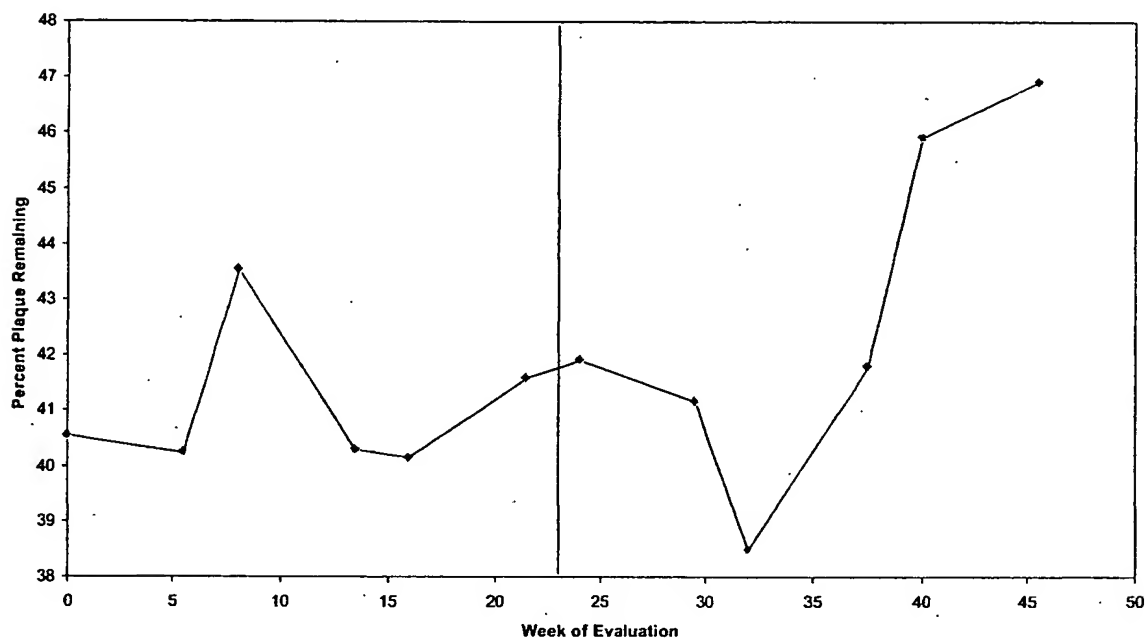**Appendix F.** Time Trend of Percent Plaque Remaining - Population 1 Data

Time Trend of Percent Plaque Remaining
Population 1 Data

- The horizontal axis measures the number of weeks since the onset of the evaluation.
- Week 0 represents Period 1, initial recall.
- The 5 and 6 week recalls for each period have been averaged.

Appendix G. Time Trend of Percent Plaque Remaining - Population 2 Data

Time Trend of Percent Plaque Remaining
Population 2 Data

- The horizontal axis measures the number of weeks since the onset of the evaluation.
- Week 0 represents Period 1, initial recall.
- The 5 and 6 week recalls for each period have been averaged.
- Dotted vertical line represents a cursory polishing of the teeth of all subjects in Population 2, immediately following Period 3. This treatment was administered at the request of the handicapped peoples' administrative board. The reason given was that the subjects generally received oral prophylaxis procedures each 6 months, and they desired to maintain this regimen. The polishing given appeared to have no effect on subsequent evaluation periods.